

1.0 Abstract

Title

Levodopa Carbidopa Intestinal Gel Home Titration using Telemedicine: Evaluation of use of Resources.

Keywords

Advanced Parkinson's disease, levodopa-carbidopa intestinal gel, telemedicine, home titration, health care resource utilization.

Rationale and Background

Levodopa-carbidopa intestinal gel (LCIG), Duodopa,[®] is intended for continuous infusion in advanced Parkinson's disease patients and allows individualised dosing. Lack of beds in Swedish hospitals for inpatient LCIG titration may delay start of LCIG treatment. Telemedicine (TM) offers an alternative titration procedure, allowing start of LCIG infusion at home.

Research Question and Objectives

The primary objective of this Post Marketing Observational Study (PMOS) was to evaluate the use of resources, measured as number of contacts and time spent by the Duodopa Nurse Specialist (DNS), the Investigator, and the TM technician (technician), during titration of LCIG at home using TM.

Secondary objectives:

To describe the total time for titration.

To measure the amount of patients' free time spent on daily activities other than LCIG titration

To describe the technical feasibility of the TM communication for home titration of LCIG

To describe the TM experience from the perspective of the Health Care Professionals (HCPs), patients and caregivers

To document the global improvement in PD symptoms at the time for decision on LCIG PEG/J surgery.

To record the health care utilization outside the TM care chain

Study Design

The data for this open-label, multicenter PMOS was to be collected from centers located in Sweden.

The data collection period for each individual patient was to start upon decision of LCIG treatment (baseline) and end when LCIG titration period was complete. The patients together with their caregiver were to be interviewed on their experiences post titration.

LCIG titration period was defined as: from start of the pump after application of the naso-jejunal tube (Day 1) until Investigator's decision on PEG/J placement or termination of LCIG treatment.

Setting

The data in this open-label, multicenter PMOS was collected in Sweden. There were 4 centers included in the study. Data collection started on 09 September 2013 (First Patient In) and data collection ended on 07 November 2014 (Last Patient Out).

Subjects and Study Size, Including Dropouts

The number of patients to be enrolled was approximately 10-15. Approximately 4 sites were to be participating in the study. Planned enrollment for each site was approximately 3-5 patients.

Planned: 10-15 patients

Actual: 15

Analyzed: 15 patients

Variables and Data Sources

Data was collected on electronic CRF (eCRF) through a secure internet based system. Each user received a unique login ID for the data collection. Only the patient's study specific number identified the patient in the eCRF.

All analyses were to be performed on the Full Analysis Set (FAS), defined as all patients that started the LCIG titration.

Results

Patients' median age was 67 (range: 52-73) years and median time since diagnosis was 10 (range: 7-23) years. Median time between LCIG initiation and end of TM assisted titration was 2.8 (range: 2.0-13.8) days. Overall median time required for home titration by neurologists, nurses and patients was 74 (range: 29-112) min, 5 hrs 49 min (range: 2 hrs 46 min – 10 hrs 3 min) and 8 hrs 53 min (range: 4 hrs 11 min – 14 hrs 38 min), respectively. According to post titration inquiry, neurologist and nurses considered the time for communication with patients to be less (60%, 93%) or equal (40%, 7%) compared to hospital titration. TM allowed patients 92% free time spent on daily activities other than LCIG titration from start to end of titration. Technical problems associated with TM contacts were rare (7%), mostly related to digital link, and quickly resolved. Patients, neurologists and nurses were satisfied using TM. No Serious Adverse Events and only one device complaint was reported.

Discussion

TM assisted LCIG titration at home was resource efficient, technically feasible, safe, and appreciated by patients, neurologists and nurses.

Marketing Authorisation Holder(s)

AbbVie AB